Our Vision is a U.S. military force that is fully sustained to fight and win in any CBRN battlespace worldwide

Next Generation Diagnostic System Increment 1 Deployable Component Industry Day

April 3, 2012

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Chemical Biological Medical Systems

NGDS Increment 1 Deployable Component Industry Day Agenda

Topic	Start	Finish
April 3, 2012		
Sign-in	12:30 p.m.	1:00 p.m.
NGDS Program Overview	1:00 p.m.	1:30 p.m.
NGDS RFP Overview / Q&A	1:30 p.m.	2:30 p.m.
Break	2:30 p.m.	3:00 p.m.
NGDS RFP Overview / Q&A	3:00 p.m.	5:00 p.m.
April 4, 2012		
One-on-One Meetings with NGDS/Government Contracting Personnel	7:00 a.m.	12:00 p.m.
End of Conference		12:00 p.m.

Purpose of the Industry Day Conference

- **To Improve the RFP**
  - Soliciting and addressing industry questions and concerns
  - Identifying areas of ambiguity
- **To improve the quality of submissions by ensuring common understanding**
  - Programmatic intent and intended use of the delivered capability
  - Government's requirements in the Section C Statement of Work
  - Proposal Instructions in Section L

Disclaimer

- **Discussions today by Government officials involved in the NGDS Acquisition should not be considered a guarantee of the Government's course of action in proceeding with the program**
- **The information shared today reflects current Government intentions and is subject to change based on a variety of circumstances. The formal solicitation, when issued, is the only document that should be relied upon in determining and responding to the Government's requirements**
- **Any costs incurred prior to receipt of a**

Ground Rules

- **Badges:**
  - NGDS Program Team: Gold
  - Industry: White
  - Other Government: Blue
- **No Side Bars with NGDS Program Team**
- **Other Government:**
  - Questions from Other Government must be submitted via index card only and may not be answered publically
  - Other Government personnel must make room for Industry seating at the front
- **No recording devices**
- **Pick up 1 on 1 meeting appointments at registration table**

Ground Rules

- **Questions and Answers**
  - Advance questions provided by 2 Apr 2012 will be addressed in the program brief and posted to the website
  - Questions may be submitted at the microphone during the brief but must also be written on an index card and submitted. These questions will be answered on the spot, after the break, or be deferred to posting to the website
  - Questions written on index cards can be submitted to the NGDS team during the brief and will be answered after the break, as time permits today, or be deferred to posting to the website
  - Questions submitted during 1-on-1 discussions will be answered on the spot if possible and posted to the website
  - Questions submitted will be anonymized (except those

Ground Rules

- **Briefs, questions and official answers to all questions will be published on the NCD website**
  - Notification provided via FedBizOpps website
- **The Final RFP shall supersede all previous discussions and documentation**

NGDS Increment 1 Deployable Component Program Overview

NGDS Vision

Diagnostic

Environmental

Infectious Disease

CBRN Defense

Host-Response Biomarkers

Chemical & Radiological Exposures

NGDS Family of Systems

Far Forward

Deployable Labs

Fixed Facilities

NGDS Increment 1 Fundamental Approach

- **In order for NGDS components to be affordable to the DoD and logistically supported by the Services, NGDS must have the widest possible routine health care and preventive medicine application so that, if needed for a CBRN threat contingency, the system will be operational, assays will be on-hand and within their expiration date and the operators will be trained and proficient**
- **To the maximum extent possible, the NGDS program will facilitate adoption of NGDS components as common solutions for the Federal Government (not just DoD)**

NGDS Initial Capabilities Document (ICD) Program Requirements

- **CBRN Field Analytics ICD, 12 Jan 2010**
  - Provide reliable identification/diagnostic results for traditional and non-traditional chemical, biological (bacteria, viruses, toxins), and radiological agents/precursors from both environmental and clinical samples
- **Infectious Disease Countermeasures ICD, Feb 2007**
  - Diagnose the causative agent of disease to inform treatment decisions, identify emerging and re-emerging infectious disease threats
  - Survey for the presence of disease using non-clinical systems to anticipate, detect, identify, and quantify, disease-causing organisms

NGDS Increment 1 On-Going Requirements Development and Uncertainty

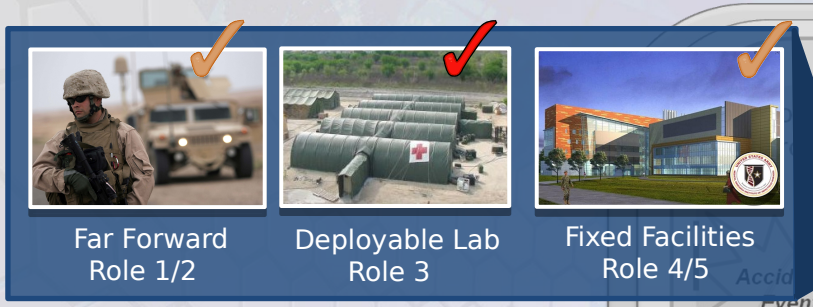
- **Two more requirements documents coming**
  - Capability Development Document
    - Provides first NGDS-specific requirements
    - Currently in Draft - expected to be completed Jul - Dec 2012
    - Discussion of which Biological Warfare Agent (BWA) in vitro diagnostic (IVD) tests will be required as initial capability threshold
    - Current program direction is Anthrax and Viral Hemorrhagic Fevers (Ebola/Marburg)
    - Potential revision to Anthrax, Plague, Tularemia, Q-Fever and VHF
  - Capability Production Document
    - Defines final threshold requirement for Milestone (MS) C
    - Expected to be completed 12 months prior to MS C
- **Management of Requirements Uncertainty**
  - Contract Options
  - Interim Program Reviews (IPR) conducted with Milestone Decision Authority (MDA) after each completed requirement document to assess acquisition approach and test approach

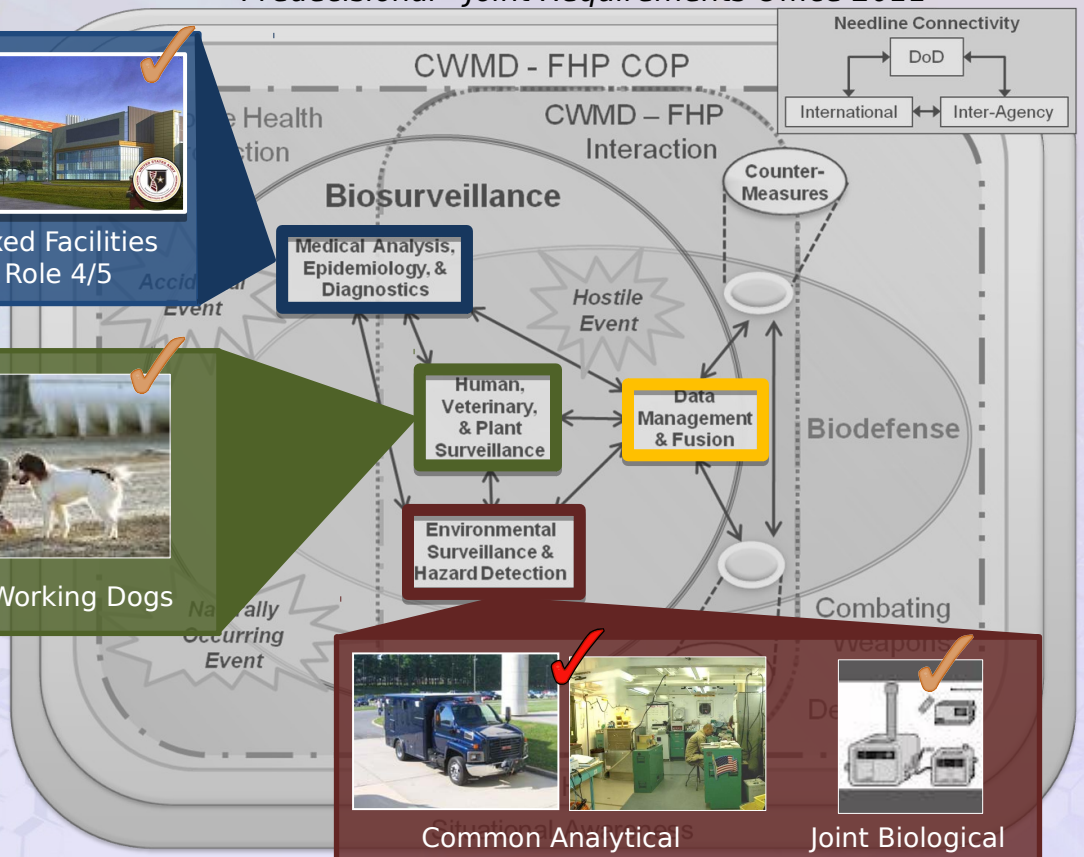
NGDS Role in Biosurveillance

"Integrated global diagnostics system that will rapidly determine and identify any threat in a clinical or environmental sample, thus providing a foundation for swift and decisive responses." *

* DRAFT DoD Diagnostic Strategic Roadmap 20111213

Predecisional - Joint Requirements Office 2011





✓ Expected Integration / Adoption of NGDS Increment 1

✓ Potential Integration / Adoption of NGDS Increment 1

NGDS Deployable Component Concept of Operations

- **NGDS Increment 1 Mission:**
  - Support near-real-time patient treatment decision making
  - Support CBRN Situational Awareness
  - Support disease surveillance
- **NGDS Increment 1 CONOPS:**
  - Rapidly process/analyze remotely collected human clinical samples with FDA-cleared diagnostic systems and qualified assays for diagnostic, surveillance and environmental applications
  - Operate in deployed medical environments, forward deployed laboratories or as reachback in support of deployed operations

NGDS Increment 1 Acquisition Strategy Summary

- **Streamlined acquisition approach**
  - Proceed from Milestone (MS) A to MS C / Full Rate Production (FRP)
- **Robust Technology Development (TD) phase resulting in initial capability (FY12 through FY15 or FY16)**
  - Competitive Prototyping (CP)
  - Initial BWA diagnostic assay and network communication qualification
  - Integration with Common Analytical Laboratory System (CALS) and Joint Biological Tactical Detection System (JBTDS)
- **Production and Deployment (PD) Phase (FY15 or FY16 to FY18)**
  - Fielding of diagnostic capability to Army, Air Force and Navy combat health support units by NGDS Program
  - Fielding of hardware to environmental users by CALS and JBTDS programs
  - Continued capability growth
    - Additional diagnostic, surveillance and environmental assays
    - Shipboard qualification
    - Additional network integration
  - Replacement of all JBAIDS systems beginning FY17

NGDS Increment 1 Acquisition Strategy: Competitive Prototyping

- **Competitive Prototyping (CP) Phase (technically the beginning part of the program's TD Phase)**
  - Contract Base Period with a few concurrent option tasks
  - Estimated 3-4 candidate systems based on available funding and proposal responsiveness
  - Purpose: Promote cost competition and allow Government to get a deeper understanding of both the Company's and system's capabilities
  - CP Phase Scope (includes both Contractor and Government work)
    - Technical Assessments
    - Operational Assessments
    - Risk Assessments
    - Early Integration (CALS, Networks)

NGDS Increment 1 Acquisition Strategy: Competitive Prototyping Phase

- **Early Operational Assessment – hands on evaluation of the Contractor's system (using commercially available assays) by Warfighters in an operational mission environment and scenario**
- **Assess the speed of Contractor assay optimization and the performance of the resulting optimized assay**
- **Assess the Contractor's pre-IDE application for the development of BWA in-vitro diagnostic (IVD) assays and the FDA's response**
- **Developmental Testing (DT) to evaluate the system's suitability and safety for use in the intended military operational environment and the system's compatibility with a broad range of clinical and environmental sample types**
- **Manufacturing and Regulatory assessments of the Contractor's capacity for future work**
- **Feasibility assessment for the adaptation of Contractor's technology to tactical applications ("Tactical Variant")**

NGDS Increment 1 Acquisition Strategy: Technology Development

- **Technology Development (TD) Phase (the remaining part of the program's TD Phase)**
  - First Option Ordering Period
  - Estimate one candidate system based on available funding
  - Purpose: Build capability required to meet MS C threshold requirements
  - TD Phase Scope (includes both Contractor and Government work)
    - IVD and Environmental assay development and qualification
    - Technical Assessments
    - Operational Assessments
    - Integration (CALS, Possibly JBTDS, Networks)

NGDS Increment 1 Acquisition Strategy: TD Phase

- **Final Operational Test to qualify the COTS platform and the initial BWA IVD assay in the Combat Support Hospital operational environment**
- **Completion of all BWA IVD assays/software revisions needed for NGDS MS C**
- **Completion of all BWA Environmental assays needed to support CALS and/or JBTDS Engineering and Manufacturing Development phase component and system level testing and MS C / Low Rate Initial Production decision**
- **Continued Developmental Testing**
- **System integration with CBRN and medical information system networks**
- **Decision to begin additional BWA IVD development beyond MS C threshold requirements**
- **Decision to begin other non-BWA IVD and Environmental assay development (funded by Government partners)**
- **Decision to develop Tactical Variant alpha and beta prototypes, depending on feasibility and JBTDS program needs**

NGDS Increment 1 Potential Development Partners

- **Assays (Developer's Toolkit and Framework for Transition)**
  - U.S. Army Medical Research and Materiel Command (USAMRMC)
  - U.S. Department of Health and Human Services - Biomedical Advanced Research and Development Authority
  - U.S. Department of Homeland Security (DHS)
  - U.S. Army Public Health Command (USAPHC)
  - Armed Forces Health Surveillance Center (AFHSC)
  - Joint Science and Technology Office for Chemical Biological Defense
  - Defense Advanced Research Projects Agency
  - JPM Guardian CALS Program
  - JPM Biological Defense JBTDS Program
- **Network Connectivity**
  - JPM Information Systems
  - Defense Health Information Management System (DHIMS)
  - Defense Health Services Systems PEO (DHSS)

NGDS Increment 1 Capability at MS C / FRP

- **Expected Capability at NGDS Inc 1 MS C / FRP**
  - System suitable and affordable for use at Land based Role 3 and higher medical units
  - System capable of supporting diagnostic, surveillance and environmental assays
  - Threshold BWA IVDs for MS C
    - Early FY15 MS C: Anthrax and Viral Hemorrhagic Fever (VHF) (Ebola/Marburg)
    - OR
    - Late FY15 to Mid FY16 MS C: Anthrax, Plague, Tularemia, Q-Fever and VHF
  - Access to COTS diagnostic and qualified environmental assays
  - Connectivity to JWARN and Medical networks

NGDS Increment 1 Acquisition Strategy: PD Phase

- **Production and Deployment (PD) Phase (everything after MS C including additional development)**
  - Additional Option Ordering Period
  - One candidate system
  - Purpose: Field threshold capability, continue to build capability
  - PD Phase Scope (includes both Contractor and Government work)
    - System and assay production and support
    - IVD and Environmental assay development and qualification
    - Shipboard Operational Assessments
    - Integration (Shipboard, Possibly JBTDS, additional networks)

NGDS Increment 1 Acquisition Strategy: PD Phase

- Produce and field systems and consumables
- Provide for logistical support to fielded systems
- Integration, test and qualification for shipboard applications of the commercial system
- Decision to begin additional BWA IVD development beyond NGDS MS C threshold requirements
- Decision to begin additional BWA Environmental assay development beyond CALS/JBTDS MS C threshold requirements
- Decision to begin other infectious disease IVD and Environmental assay development (funded by Government partners)
- Decision to develop pre-production, LRIP and FRP Tactical Variant, if feasible and desired by the Government
- Decision to integrate system with additional CBRN and medical information system networks

NGDS Increment 1 Contract Strategy Summarized

- **Single RFP covering all program phases**
- **Release RFP (~20 Apr 2012)**
  - Language incorporated to procure bid samples during source selection to permit Government to conduct and pay for required testing, including materials needed
- **Proposals Due (~23 May 2012)**
  - One bid sample provided with proposal
  - Initiate system evaluations
- **Competitive range determination (~16 Jun 2012)**
  - Additional bid sample purchase orders / contracts [6-10 systems & 3-5 consumables per proposal] (see above)
  - Initiate developmental testing
  - Data will not be used to support initial award
- **Contract Award (~30 Jul 2012)**

NGDS Increment 1 Program Schedule

NGDS Increment 1 Schedule

	FY12				FY13				FY14				FY15				FY16				FY17			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Requirements		MS A		IPR	TD Phase			IPR							MS C/FRP		TD/ PD Phase			Shipboard FRP / Alternate MS C Date				
NGDS Milestones & Phases				NGDS CDD			NGDS CPD						BA /VHF Only				BA/YP/FT/Q/VHF							
CALS and JBTDS Milestones and Phases	CALS TD Phase					MS B			EMD Phase			MS C/LRIP			FRP		P&D Phase						
	JBTDS TD Phase						MS B		EMD Phase										MS C/LRIP	P&D Phase				
System Engineering Technical Reviews						PDR		CP Review		Interim Tech Review			CDR											
Major Contract Events			RFP			CTQ Award		First Option Period							COTS FRP Option					Shipboard Option				
Competitive Prototyping / Risk Reduction						Competitive Prototyping																		
Test Documents	TES		TEMP																					
					EOA Plan		DTR	OAM		OT Plan		OER	BLRIP					OER	OA					
Capability Development						NGDS/CALS/JBTDS BWA Assay Optimization																		
						Network Connectivity Development																		
Testing													BWA Assay FDA Clearance											
						DT (with Network)									1st FDA BWA Clearance		SHIP DT							
						EOA						OT					SHIP OT							
Production																	COTS Analytical System and Network Interface Device Production				Shipboard Integration Production			

Program Points of Contact

- COL Charles Millard, PhD JPM CBMS
- Jason Roos, PhD Joint Product Director (JPD) CBMS-BSV
- Jennifer Dabisch Deputy JPD CBMS-BSV
- Adam Becker NGDS System Manager
- Jim Karaszkiewicz, PhD NGDS Lead Scientist
- Roger Lisk NGDS Logistics WIPT Lead
- Michael Retford NGDS Systems Engineering WIPT Lead
- Royce Bruce NGDS Test and Evaluation WIPT Lead
- Fedora Daye NGDS Regulatory Lead
- Michael Smith, PhD Critical Reagents Program Director
- Steven Kaminsky NGDS/CALS/JBTDS Synchronization Manager
- Richard Alves Contracting Officer, ACC-APG NCD
- John Conlin Contract Specialist, ACC-APG NCD

NGDS Increment 1
Request for Proposal

NGDS Increment 1 Draft RFP Scope

- **Proposed Draft RFP Content**
  - Section B: Supplies or Services and Prices
  - Section C: Statement of Work
  - Section J:
    - NGDS Performance Spec (P-Spec) (Inclusive of CALS requirements)
    - JBTDS P-Spec (to support Tactical Variant Feasibility Study pricing)
  - Section L: Instruction to Bidders
    - Organization and content of the proposal
  - Section M: Evaluation Factors for Award
    - Evaluation Factors and relative importance for Source Selection
  - CDRLs
  - Helpful Materials
    - CP Phase Timeline Cartoon
    - Government notional Integrated Master Schedule
    - Template STP56 GFI data template

RFP Section C (SOW)

- **Section C.1 and C.2 NGDS Overview**
  - Applicable guidance documents, standards, intent and descriptions
  - No deliverables or priced tasks
- **Section C.3 Organization**
  - Priced tasks
  - C.3.1 CP Phase: Base Period of Performance (PoP)
  - C.3.2 TD Phase: Options for remainder of TD phase to MS C
  - C.3.3 PD Phase: Options for Post MS C
  - Redundancies will be taken care of in Section B CLIN Structure
- **Section C.3.X Organization**
  - C.3.X.1 - Program Management
  - C.3.X.2 - Deliveries
  - C.3.X.3 - Development and Testing
  - C.3.X.4 - Studies and Reports
  - C.3.X.5 - Logistics

RFP Section C (SOW)

- **Section C.1 and C.2: NGDS Overview**
  - Applicable guidance documents, standards, intent and descriptions
  - No deliverables or priced tasks
- **Section C.3.1: Base Period**
  - Delivery of test items / consumables / logistical and technical support
  - Demonstration of Rapid Assay optimization
  - Studies supporting follow-on optional tasks
- **Section C.3.2: Options for remainder of TD phase to MS C**
  - Delivery of test items, consumables, logistical and technical support
  - Delivery of threshold FDA cleared BWA IVD assays
  - Delivery of BWA environmental assays in support of CALS program
- **Section C.3.3: Options for Post MS C**
  - Delivery of production items, consumables, logistical and technical support
  - Many repeated tasks from Part III for additional assays, as necessary

RFP Section C (SOW)

- **Delivery and Development Tasks in all phases are separated into 4 sub-sections**
  - BWA IVD
  - Non-BWA IVD
  - BWA Environmental
  - Non-BWA Environmental
- **BWA vs. Non-BWA**
  - Relates primarily to who provides funding to execute task (PL103-160)
  - Syndromic IVD approaches are still desired, when feasible, regardless of BWA/non-BWA distinctions
- **IVD vs. Environmental**
  - Different test and regulatory standards
  - FDA usually requires separable user interface software between IVD tests and Environmental tests for systems capable of running both
  - Environmental supports CALS/JBTDS, public health, veterinary communities

NGDS Increment 1
Draft RFP Section C

- **SOW Section C.3.1 - Base Period**
  - Program Management (weekly telecons, monthly reports, IPRs, EVM)
  - Delivery of up to 33 commercial systems w/spare parts and COTS assays from each vendor
  - Provide training, CLS, on-site and reachback technical support
  - Obtain personnel and facility security clearances
  - Develop and deliver optimized BWA assays and software update
    - Concurrent Options for BA, YP, FT, Q and VHF prototype singleplex or multiplex assays - spans the range of OSD/JRO discussion
    - Optimization in clinical and environmental sample types, as applicable
  - Prepare Pre-IDE application for BA and VHF IVD and conduct pre-IDE meeting with FDA

NGDS Increment 1
Draft RFP Section C

- **SOW Section C.3.1 – Base Period Continued**
  - Facilitate Government Risk assessments
    - Manufacturing (and Development) Readiness Assessment (MRA)
    - Regulatory Audit
  - 5 Technical studies
    - Multiplex IVD assay configuration (BWA only, ID only and BWA and ID)
    - Multiplex BWA Environmental assay configuration
    - Multiplex ID Environmental assay configuration
    - Tactical Variant Feasibility vs. JBTDS P-Spec
    - CLIA-waived study
  - "Engineering Studies", as needed - engineering hours for minor modifications to hardware/software

NGDS Increment 1 Draft RFP Section C

- **Section C.3.2- Contract Options post-CP to MS C**
  - Program Management (weekly telecons, monthly reports, IPRs, EVM)
  - Deliver up to 75 commercial systems w/ spares to support assay development, clinical trials, network integration, DT and Operational Testing (OT)
  - Deliver COTS and prototype BWA assays as needed
  - Options to complete FDA clearance of BA, YP, FT, Q and VHF IVD if started in Base period - including software revisions
  - Options to begin assay optimization for YP, FT, Q, VHF if not started in base period - progress to FDA clearance, if funded
  - Develop and conduct Contractor Verification Testing (CVT) for ALL required BWA environmental assays (~14

NGDS Increment 1
Draft RFP Section C

- **Section C.3.2- Continued**
  - Conduct network integration minor modifications, as needed to complement JPM-IS/SSA work
  - Develop and deliver Tactical Variant Alpha and Beta Prototypes
  - Accommodate Partner funded IVD or environmental assay new starts
  - Provide CLS, on-site and reach back support for test items
  - Develop proposed logistics tools for asset tracking, failure and maintenance tracking, consumable ordering, etc.
  - "Engineering Studies", as needed - engineering hours for minor mods
  - Implement "Developers Tool Kit“, as required

NGDS Increment 1
Draft RFP Section C

- **Section C.3.3- Contract Options post-MS C**
  - Deliver up to 1,500 NGDS platforms/systems
  - Deliver commercial, prototype BWA, completed BWA IVD and BWA Environmental assays, as needed
  - Complete FDA clearance IVDs started in TD phase, if not completed for MS C
  - New start BWA IVD development and clearances, as needed
  - New start BWA environmental assay development and testing, as needed
  - Conduct network integration mods, as needed to complement JPM-IS / SSA work
  - Conduct shipboard / CALS integration mods, as needed

NGDS Increment 1
Draft RFP Section C

- **Section C.3.3 - Contract Options post-MS C**
  - Develop and Deliver Tactical Variant Pre-Production Prototypes, LRIP and FRP units
  - Conduct Tactical Variant IVD Bridging Study, if needed
  - Provide CLS and reach back support for operational systems and test items
  - "Engineering Studies", as needed - engineering hours for minor mods
  - Accommodate Partner funded IVD or environmental development assay new starts
  - Accommodate Federal and DoD system, assay, parts and CLS purchases, as needed
  - Implement parts obsolescence mitigation actions, as needed
  - Implement Bankruptcy/Buyout protection, as needed

Section L: Instruction to Bidders
Section M: Evaluation Factors for Award

- **Factor Weightings**
  - Technical > Program Management > Past Performance > Cost/Price
- **Technical Factor**
  - **L.4.1 / M.3.2.1.1. Statement of Work (SOW)** - provide a written narrative demonstrating compliance with the SOW (Section C)
  - **L.4.2 / M.3.2.1.2. Performance Specification** - provide a written narrative demonstrating compliance with the Performance Specification. The Performance Specification is not a requirement for performance, but a benchmark for evaluation purposes.
  - **L.4.3 / M.3.2.1.3.** Commercial Assay Capability – provide a listing of all commercially available, developmental and planned clinical and environmental assays

Section L: Instruction to Bidders
Section M: Evaluation Factors for Award

- **Program Management Factor**
  - **L.5.1 / M.3.2.2.1. Contractor Work Breakdown Structure(CWBS), Integrated Master Plan (IMP) and Integrated Master Schedule (IMS)**
  - **L.5.2 / M.3.2.2.2. Risk Management and Quality Management Plans**
  - **L.5.3 / M.3.2.2.3. Small Business Participation Plan**
  - **L.5.4 / M.3.2.2.4. Earned Value Management**
    - DoD EVM narrative and implementation plan
    - A Validated or Certified DoD EVMS
- **Past Performance Factor**
- **Cost/Pricing Factor**
- **Bid Sample**
  - Provide one complete FDA cleared/approved system and one of each FDA cleared/approved IVD assay

Desired Feedback

- **Anticipated contract type**
  - ID/IQ with a "hybrid" CLIN structure including FFP and Cost (likely CPFF)
- **Special requirements**
  - Adequate Contractor accounting system for Cost-type CLINs
  - Applicability of EVMS for cost-type CLINs
  - Pricing production options
  - Pricing tactical variant options
- **Providing 1 bid sample as part of proposal**
- **Providing additional bid samples at competitive range**
- **Requested Contractor proposed CLIN structure for COTS and future BWA assay**

Desired Feedback

- **Program Schedules**
  - COTS system and assay deliveries
  - Assay Optimizations
  - Pre-IDE Applications
- **Capacity to conduct parallel IVD trials affecting program MS C schedule**
- **Accommodation of Government vs. Commercial BWA assay designs**
  - Ability to adapt GFI information
  - Ability to provide information about Contractor BWA assays
- **Proposed Contractor Logistic Support (CLS) concepts**
- **Open architecture**